

REMARKS

I. Status of Claims

Claims 1-16, 26, and 27 are pending in this application. Claims 17-25 have been cancelled without prejudice or disclaimer. Claims 1, 4, 6-9, 12, 14, and 15 have been amended. Support for the amendments can be found in the specification for the following reasons.

Support for adding the substituent -OH in defining "Ar" is found in the specification as follows. Specifically, the specification discloses, on page 4, that the substituent of Ar can be -OR₁, and that R₁ can be hydrogen. In the original claims, for example, original claim 6, the substituent of Ar can be -OH. Furthermore, the specification discloses, for example, compound 22 on page 71, compound 32 on page 72, compounds 40, 41, and 43 on page 74, compound 48 on page 75, compounds 52 and 53 on page 76, compound 155 on page 95, and compound 164 on page 97, wherein one of the substituents of Ar is -OH. Thus, the amendment does not add new matter.

Support for adding "wherein when Ar is a 9-membered bicyclic heterocycle containing one or more heteroatoms selected from N, O and S, Ar is unsubstituted" is found in the specification, for example, at pages 3 and 4. There, the specification discloses that Ar "is unsubstituted or at least monosubstituted aryl or heteroaryl," wherein "heteroaryl is a 5 to 10-membered . . . bicyclic heterocycle containing one or more heteroatoms selected from N, O and S." Specification, pages 3-4. The specification also discloses, for example, compound 159 on page 96 and compound

176 on page 98, wherein the Ar is an unsubstituted, 9-membered bicyclic heterocycle.

Accordingly, this limitation does not introduce new matter.

New claims 26 and 27 have been added. Each of the compounds recited in new claim 26 has support in the specification as shown below:

“6-(4-methoxy-phenyl)-3-oxo-2,3-dihydro-pyridazine-4-carboxylic acid (3-pyridin-3-yl-propyl)-amide” is compound 29, disclosed on page 72 of the specification;

“6-(4-hydroxy-3-methoxy-phenyl)-3-oxo-2,3-dihydro-pyridazine-4-carboxylic acid 4-chloro-benzylamide” is compound 41, disclosed on page 74 of the specification and in original claim 8;

“6-(4-hydroxy-3-methoxy-phenyl)-3-oxo-2,3-dihydro-pyridazine-4-carboxylic acid (3-pyridin-3-yl-propyl)-amide” is compound 49, disclosed on page 75 of the specification;

“6-(4-methoxy-phenyl)-3-oxo-2,3-dihydro-pyridazine-4-carboxylic acid 4-chloro-benzylamide” is compound 51, disclosed on page 75 of the specification;

“4-[5-(4-chloro-benzylcarbamoyl)-6-oxo-1,6-dihydro-pyridazin-3-yl]-3-methoxy-thiophene-2-carboxylic acid” is compound 197, disclosed on page 102 of the specification;

“6-(5-carbamoyl-4-methoxy-thiophen-3-yl)-3-oxo-2,3-dihydro-pyridazine-4-carboxylic acid 4-chloro-benzylamide” is compound 207, disclosed on page 103 of the specification); and

“4-([6-(4-hydroxy-3-methoxy-phenyl)-3-oxo-2,3-dihydro-pyridazine-4-carbonyl]-amino)-methyl)-benzoic acid” is compound 225, disclosed on page 106 of the specification and in original claim 8.

Further, support for new claim 27 is found in the specification, such as original claim 9.

Therefore, Applicants have not introduced any new matter by the amendment, nor does the amendment raise new issues or necessitate the undertaking of any additional search of the art by the Examiner.

II. Rejection under 35 U.S.C. § 112, First Paragraph, Written Description

The Examiner has maintained the rejection of claims 1-28 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Final Office Action, pages 2-4. Specifically, the Examiner alleges that the new provisos recited in claims 1 and 9, *i.e.*, provisos (2) and (3), lack description. *Id.* at page 2. The Examiner suggests deleting substituents from formula (1) to overcome the rejection. *Id.* at page 4.

Applicants respectfully disagree with the Examiner. However, solely to advance the prosecution of this application, Applicants have deleted provisos (2) and (3) recited in claims 1 and 9 as set forth above. Accordingly, Applicants respectfully request this rejection be withdrawn.

III. Rejection under 35 U.S.C. § 112, First Paragraph, Enablement

The Examiner has also maintained the rejection of claims 9-25 under 35 U.S.C. § 112, first paragraph, for lack of enablement for the reasons of record. Final Office Action, pages 4-8. In addition, the Examiner states that the Rule 132 Declaration or the article submitted by Applicants “does not link the inhibition of CDK2 to the treatment of

cancer in general.” *Id.* at page 9. Further, the Examiner concludes that the disclosure at pages 110-111 of the specification shows “the inhibition of CDK2, but there is no correlation between the inhibition and the treatment of cancer in general.” *Id.* The Examiner suggests canceling the rejected claims. *Id.*

A. Claims 9-16

Applicants respectfully disagree with the Examiner and traverse the rejection of claims 9-16 for the reasons of record and the following additional reason.

In the final Office Action, the Examiner fails to point to any evidence rebutting the correlation between the inhibition of the kinase CDK2 *in vitro* and *in vivo*, which Applicants submit supports the enablement of claims 9-16. The Examiner’s analysis in the final Office Action, including the discussion of the Wands factors, appears directed to the rejection of claims 17-25, which recite methods of treating cancer. Those assertions, however, do not establish the nonenablement of claims 9-16, which are directed to the method for inhibiting CDK2 *in vivo*. Therefore, Applicants respectfully request that the Examiner withdraw the rejection of claims 9-16.

B. Claims 17-25

Applicants also respectfully disagree with the Examiner’s rejection of claims 17-25. However, solely to advance the prosecution of this application, Applicants have cancelled claims 17-25. Therefore, this rejection of claims 17-25 is moot. Applicants request that the Examiner withdraw it.

IV. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application, and the timely allowance of the pending claims.


If the Examiner believes a telephone conference would be useful in resolving any outstanding issues, the Examiner is invited to call the Applicants' undersigned representative at (202) 408-4218.

If there is any fee due in connection with the filing of this response, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

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By: 

Ningling Wang
Reg. No. 52,412